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Assistant Commissioner for Patents
Washington, D.C. 20231

On 25 Nov. 2002

TOWNSEND and TOWNSEND and CREW LLP

By: Mahmoud Adigat

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12/4/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Glenna C. Burner et al.

Application No.: 09/292,758

Filed: April 14, 1999

For: NUCLEIC ACID SEQUENCES
AND PROTEINS ASSOCIATED WITH
AGING

Examiner: B. Sisson

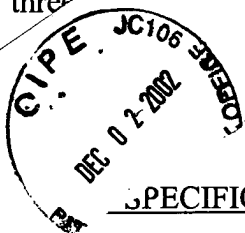
Art Unit: 1634

AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed May 23, 2002, please amend the above-identified application as follows. A petition for extension of time to respond for three months, from May 23, 2002, to November 23, 2002, is filed herewith. Appendix 1 shows all changes made. All pending claims are presented



SPECIFICATION:

Please substitute the title of the application on page 1 with the amended

version:

--NUCLEIC ACID SEQUENCES ASSOCIATED WITH AGING--

12/04/2002 BABRAHA1 00000079 201430 09292758

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IN THE CLAIMS:

Please ~~cancel~~ claims 1, 6, 8, 38, 55, and 62.

Please ~~amend~~ claims 2, 3, 9, 10, 29, and 31 as follows:

2. (once amended) An isolated nucleic acid comprising a polynucleotide sequence associated with the senescence of a cell, wherein the sequence has at least 85% sequence identity with SEQ ID NO:1.

3. (once amended) The isolated nucleic acid of claim 2 wherein the sequence has at least 95% sequence identity with SEQ ID NO:1.

9. (once amended) An isolated nucleic acid comprising a polynucleotide sequence associated with G0-arrested cells, wherein the sequence has at least 85% sequence identity with SEQ ID NO:2.

10. (once amended) The isolated nucleic acid of claim 9 wherein the sequence has at least 95% sequence identity with SEQ ID NO:2.

29. (twice amended) A kit for detecting whether a cell is undergoing senescence, said kit comprising:

a probe which comprises a polynucleotide sequence selected from the group consisting of SEQ ID NO:1, 2, 37, 61, 67, 69, 70, and 73; and
a label for detecting the presence of said probe.

31. (twice amended) The kit in accordance with claim 29 further comprising a plurality of probes each comprising a polynucleotide sequence independently selected from the group consisting of SEQ ID NO:1, 2, 37, 61, 67, 69, 70, and 73; and
a label for detecting the presence of said plurality of probes.

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IN THE ABSTRACT:

Please substitute the title of the abstract on page 82 with the amended version:

--NUCLEIC ACID SEQUENCES ASSOCIATED WITH AGING--

REMARKS

I. Status of the Claims

Claims 1-3, 6-10, 29, 31-33, 38, 55, and 62 were pending. Upon entry of the present amendment, claims 2, 3, 7-10, 29, and 31-33 are under examination.

Claims 2 and 9 as amended contain elements imported from claims 1 and 8, respectively, such that they are now independent claims in proper form. Claims 3 and 10 are amended to ensure proper dependency in light of the cancellation of claims 1 and 8. Claims 29 and 31 are amended to delete SEQ ID NO:55 and substitute SEQ ID NO:38 with SEQ ID NO:37, which was the result of a typographic error during the election process. No new matter is added.

II. Objections and Claim Rejections

A. Objections

1. Title

The Examiner objected to the title of the application as non-descriptive. Applicant has amended the title for both the application and the abstract to address the issue.

2. Duplication of Claims 29, 32, 38, 55, and 62

Claims 29, 32, 38, 55, and 62 were objected to as the Examiner alleged that they are duplicative for claiming kits with the same components although intended for different use.

Claims 38, 55, and 62 are canceled. Applicant respectfully notes that claims 29 and 32 are not duplicative. Claim 29 relates to a kit comprising a probe selected from SEQ ID NOs:1, 2, 37, 61, 67, 69, 70, and 73 and a label for detection of the

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probe. Claim 32 relates to a kit comprising *a plurality* of probes independently selected from SEQ ID NOs:1, 2, 37, 61, 67, 69, 70, and 73 and immobilized on a solid support, as well as a label for detecting the plurality of probes. Applicant thus respectfully requests the withdrawal of the objection to claim 32 for alleged duplication to claim 29.

B. Claim Rejections

1. Claim Rejections under 35 USC §112 First Paragraph

Claims 1-3 and 6-10 were rejected under 35 USC §112 first paragraph for alleged inadequate written description. Specifically, the Examiner stated that claims 1-3 and 6-10 encompass a large number of nucleic acid sequences and the specification does not reasonably suggest that Applicant had the genera of nucleic acids in possession at the time the application was filed. Applicant respectfully traverses the rejection in light of the present amendment.

Upon entry of the present amendment, the rejection for alleged failure to meet the written description requirement is applicable to claims 2, 3, 7, 9, and 10. Since all of these claims are original claims, there is thus a strong presumption that an adequate written description is present at the time of filing. MPEP §2163 (I)(A). In other words, the PTO has the initial burden of presenting evidence or reasons why persons with ordinary skill in the art would not recognize in the disclosure a description of the invention defined by the claims. *Id.*

Claims 2, 3, 9, and 10 as amended are directed to nucleic acids that have at least 85% or 95% sequence identity to disclosed SEQ ID NO:1 or 2. Claim 7 is drawn to an isolated nucleic acid comprising a polynucleotide that is related to cellular senescence and capable of hybridizing to SEQ ID NO:1 under specified conditions. The claims fully comply with the requirements for written description of a chemical genus as set forth in *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). As described by the Federal Circuit in *Lilly*, “[a] description of a genus of cDNAs may be achieved by means of . . . a recitation of structural features common to the members of the genus” *Lilly*, 43 USPQ2d at 1406. Furthermore, the court in *Fiers v. Revel*

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stated that an adequate written description "requires a precise definition, such as by structure, formula, chemical name, or physical properties." *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The claims set forth both functional elements as well as structural elements, i.e., hybridization conditions and reference sequences to which members of the claimed genus hybridize. Therefore, the claimed sequences are thereby defined via shared physical and structural properties.

The ability of a particular nucleic acid to hybridize under *given conditions* to a reference nucleic acid is a physical/structural property of the nucleic acid, because it relies upon the nucleotide sequence of the molecule (*see, e.g., Sambrook, Molecular Cloning: A Laboratory Manual*, pp. 9.47-9.51 (2nd ed. 1989); *see also* Stryer, *Biochemistry*, pp. 573 (2nd ed. 1975)). As described in Stryer, the transition between hybridization and melting of complementary nucleic acid strands is abrupt and largely sequence dependent. When the temperature of hybridization is provided, one of skill in the art would be able to predict whether or not a given sequence would hybridize to a reference sequence (*see, e.g.,* equations provided in Sambrook, *supra*). Moreover, in the same light, the percent identity of a nucleic acid to a reference sequence is a structural feature, as it relies entirely on the sequence of the molecule.

In the present application, Applicant has provided both reference nucleotide sequences, as well as hybridization conditions and sequence analysis algorithms. As required by the standard set forth in *University of California v. Eli Lilly*, these structural features are common to all of the members of the claimed nucleic acid genus. The given conditions under which the claimed genus would hybridize to a reference sequence or have a specified identity to such sequences allow persons of ordinary skill in the art to recognize the invention as claimed.

On the other hand, the Examiner has shown no evidence or reason why one skilled in the art cannot recognize the invention as defined by the claims based on sequence identity or hybridization to a reference nucleotide sequence under given conditions. Without evidence to prove otherwise, the presumption of adequate written

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description stands and a written description rejection cannot be properly maintained.
Applicant thus respectfully requests the withdrawal of the rejection.

2. Claim Rejections under 35 USC §103

Claims 29, 31, 38, 55, and 62 were rejected under 35 USC §103(a) over Thompson in view of Hillier et al. Claims 32 and 33 were further rejected under 35 USC §103(a) over Thompson and Hillier in view of Sosnowski et al. Specifically, the Examiner pointed to SEQ ID NO:55 as identical to Accession No. N53466 as disclosed by Hillier et al.

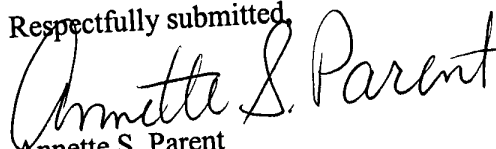
The present amendment has deleted the recitation of SEQ ID NO:55 in claims 29 and 31, whereas claims 38, 55, and 62 have been canceled. Applicant therefore respectfully requests that the rejection be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,


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